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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/665,233      | 09/17/2003  | Gilles R. G. Monif   | 1365-001            | 5452             |

4678 7590 11/03/2004

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EXAMINER

SWARTZ, RODNEY P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1645

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/665,233

Applicant(s)

MONIF, GILLES R. G.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23August2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4,6 and 15-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,15-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/04.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Applicant's Response to Office Action, received 23 August 2004, is acknowledged. Claims 1-4 and 6 have been amended. Claim 5 has been canceled. New claims 15-38 have been added.
2. Claims 1-4, 6, and 15-38 are pending and under consideration.

### **Rejections/Objections Moot/Withdrawn**

3. The objection to claims 1-4 and 6 for the abbreviation MAP is withdrawn in light of the amendment of the claims.
4. The objection to claim 5 for the abbreviation MAP is moot in light of the cancellation of the claim.
5. The rejection of claim 5 under 35 U.S.C. 112, second paragraph, indefiniteness, is moot in light of the cancellation of the claim.
6. The rejection of claim 5 under 35 U.S.C. 112, first paragraph, enablement, is moot in light of the cancellation of the claim.
7. The rejection of claims 1-4 and 6 under 35 U.S.C. 112, second paragraph, indefiniteness, is withdrawn in light of the amendment of the claims.
- 8.

### **Rejections/Objections Maintained**

9. The objection to Figure 4 under 37 CFR 1.83(a) is maintained for reasons of record.

Applicants argue that because the strains B,E, and F did not show any statistical difference in the adherence to the explants, they were not provided individually.

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The examiner has considered applicants' argument, but does not find it persuasive. The specification lists the strains and does not state that "they were not provided individually".

Therefore, the data must be placed into the Figure 4.

The objection to Figure 6 under 37 CFR 1.83(a) is maintained for reasons of record.

Applicants argue that because the strains B,E, and F did not show any statistical difference in the adherence to the explants, they were not provided individually.

The examiner has considered applicants' argument, but does not find it persuasive. The specification lists the strains and does not state that "they were not provided individually".

Therefore, the data must be placed into the Figure 6.

10. The rejection of claims 1-4 and 6 and newly added claims 15-38 under 35 U.S.C. 112, first paragraph, enablement, is maintained for reasons of record.

Applicants argue that the amendment of the claims obviate the rejection, and that the specification is sufficient in supporting the enablement of the claims.

The examiner has considered applicants arguments and amendments, but does not find them persuasive for the reasons put forth in the original rejection. The specification provides no *in vivo* examples of vaccines, only *in vitro* attachment studies.

Newly added claims 15-38 are also drawn to a method of oral vaccination and would have been likewise rejected under the same reasoning. Therefore, the newly added claims 15-38 are included in the original rejection.

### Conclusion

11. No claims are allowed.

12. Applicant's amendment adding new claims 15-38 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See

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MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

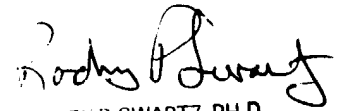
The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "Rodney P. Swartz". The signature is fluid and cursive, with the first name "Rodney" and last name "Swartz" clearly distinguishable.

RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

November 1, 2004